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Roberto A. Macina

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EXAMINER

MUMMERT, STEPHANIE KANE

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/537,694	Applicant(s) MACINA ET AL.	
	Examiner STEPHANIE K. MUMMERT	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-6, 8-9 and 16 and SEQ ID NO:12 and SEQ ID NO:13 in the reply filed on August 14, 2009 is acknowledged. The traversal is on the ground(s) that "an elected nucleic acid sequence, as well as the polypeptide encoded thereby and antibodies thereto, share the special technical feature of being useful in diagnosing cancer". This is not found persuasive because the claims of Group I are not limited specifically to the full length nucleic acid sequence or the full length sequence of the protein. Instead, the full scope of Group I also includes "nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) and (b)". Such sequences are well known in the art and due to the breadth of the scope include a variety of sequences that are not particularly related to either the protein or to the antibody directed to the protein. Therefore, the claims are not linked by a special technical feature and therefore Applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 10-15 and 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 14, 2009.

Claims 1-6, 8-9 and 16 are pending and will be examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 6, 2005 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 1 and 16 encompass nucleic acid molecules that selectively hybridize to SEQ ID NO:12, or to the nucleic acid molecule that encodes SEQ ID NO:113, a broad genus of nucleic acids that have not been properly described.

Legal Analysis

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common

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attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.).

In the instant case, while claims 1 and 16 are directed to the nucleic acid sequence encoding SEQ ID NO:113, the nucleic acid sequence comprising SEQ ID NO:12 and sequences 95% identical to (a) or (b), claims 1 and 16 also encompass nucleic acid molecules that selectively hybridize to SEQ ID NO:12, or selectively to the nucleic acid molecule that encodes SEQ ID NO:113 that have not been properly described. A large variety of sequences are reasonably capable of hybridizing or which “selectively hybridize” to a nucleic acid sequence of 2297 bases in length. Applicant has taught certain sequences which are useful to detect the mRNA which encodes SEQ ID NO:113 and therefore would hybridize to SEQ ID NO:12. These sequences include SEQ ID NO:233-235, primers and probes useful for Real Time QRT-PCR detection of SEQ ID NO:113 and four probes are generally described as present on a breast array as useful for detection of the mRNA associated with SEQ ID NO:113. However, these seven sequences are not representative of the entire scope of the broad genus of nucleic acids which are capable of selective hybridization. The specification also does not provide guidance regarding what factors influence the selective hybridization, or the length of complementarity necessary between SEQ ID NO:12 and the nucleic acid molecule claimed which would meet the limitation.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an

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indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of sequences based on the term "selectively hybridizes" without further guidance regarding the stringency of hybridization, the percent complementarity or the length of sequence necessary to meet the limitation leads to a conclusion of lack of proper written description. This is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the specific sequence comprising SEQ ID NO:12, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

Absence of a representative number of species

In the current case, the first question is what constitutes a generic claim. In this case, the generic claim includes a broad scope of nucleic acid molecules capable of selective hybridization to SEQ ID NO:12 and to the nucleic acid encoding SEQ ID NO:113. As noted above, at most, Applicant has taught certain sequences which are useful to detect the mRNA which encodes SEQ ID NO:113 and therefore would hybridize to SEQ ID NO:12. These sequences include SEQ ID NO:233-235, primers and probes useful for Real Time QRT-PCR detection of SEQ ID NO:113 and four probes are generally described as present on a breast array as useful for detection of the mRNA associated with SEQ ID NO:113. However, these seven sequences are not representative of the entire scope of the broad genus of nucleic acids which are capable of hybridizing

Absence of any structure-function relationship

The second issue is whether there is any structure function relationship which correlates a

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function with a particular structure. This question fundamentally addresses the issue of whether there is any structure which the specification demonstrates is necessarily correlated with the nucleic acid molecules which are capable of selective hybridization. Applicant has provided no sequence which is common to the nucleic acids which fall within the scope of this broad genus of nucleic acids. Since there is no common structure among the nucleic acids that are specifically associated with the unknown function of the nucleic acid, except for a role as a primer or probe, there is no structure-function relationship between the genus of nucleic acids claimed.

Conclusion

In the application at the time of filing, there is no record or description which would demonstrate possession of the genus of nucleic acids capable of selective hybridization to either SEQ ID NO:12 or to the nucleic acid encoding SEQ ID NO:113. Therefore, the claims fail to meet the written description requirement by encompassing a broad genus of nucleic acid molecules which are not properly described in the specification.

Claim Objections

Claim 16 is objected to because of the following informalities: The amendment to the claims changes the claim to state "(e) a polypeptide a polypeptide of claim 12", which repeats the phrase "a polypeptide". Appropriate correction is required.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-6, 8-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Afar et al. (WO01/31012, published March 5, 2001). Afar teaches a sequence which is upregulated in prostate cancer, 20P2H8, a protein which shares homology with heterogeneous nuclear ribonucleoproteins (hnRNP) (Abstract).

With regard to claim 1, Afar teaches an isolated nucleic acid molecule comprising: (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 113;

(b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 12;

(c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b) (see alignment below, where 20P2H8, which corresponds to SEQ ID NO:1 of Afar shares 85.7% similarity with the full length of SEQ ID NO:12 in the instant claim; see detail regarding SEQ ID NO:1 of Afar at p. 5 and p. 11, for example);

[illegible]

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Qy	557	CTCCACAGCCTGGCACGGTGGTCAGAATGCAGGGCCTGGCCTACAATACTGGAGTTAAGG	616
Db	1841	CTCCACAGCCTGGCACGGTGGTCAGAATGCAGGGCCTGGCCTACAATACTGGAGTTAAGG	1900
Qy	617	AAATTCTTAACTTCTTCCAAGGTTACCAAGTATGCAACCGAGGATGGACTTATACACACAA	676
Db	1901	AAATTCTTAACTTCTTCCAAGGTTACCAAGTATGCAACCGAGGATGGACTTATACACACAA	1960
Qy	677	ATGACCAGGCCAGGACTCTACCCAAAGAATGGGTTTGTATTTAAGGGCCCCAGCAGTTAG	736
Db	1961	ATGACCAGGCCAGGACTCTACCCAAAGAATGGGTTTGTATTTAAGGGCCCCAGCAGTTAG	2020
Qy	737	AACATCCTCAGAAAAGAAGTGTGTTGAAAGATGTATGGTGATCTTGAAACCTCCAGACACA	796
Db	2021	AACATCCTCAGAAAAGAAGTGTGTTGAAAGATGTATGGTGATCTTGAAACCTCCAGACACA	2080
Qy	797	AGAAAACCTTCTAGCAAATTCAGGGGAAGTTTGTCTACACTCAGGCTGCAGTATTTTCAGC	856
Db	2081	AGAAAACCTTCTAGCAAATTCAGGGGAAGTTTGTCTACACTCAGGCTGCAGTATTTTCAGC	2140
Qy	857	AAACTTGATTGGACAAACGGGCCTGTGCCTTATCTTTTGGTGGAGTGAAAAAATTTGAGC	916
Db	2141	AAACTTGATTGGACAAACGGGCCTGTGCCTTATCTTTTGGTGGAGTGAAAAAATTTGAGC	2200
Qy	917	TAGTGAAGCCAAATCGTAACTTACAGCAAGCAGCATGCAGCATACCTGGCTCTTTGCTGA	976
Db	2201	TAGTGAAGCCAAATCGTAACTTACAGCAAGCAGCATGCAGCATACCTGGCTCTTTGCTGA	2260
Qy	977	TTGCAAATAGGCATTTAAAATGTGAATTTGGAATCAGATGTCTCCATTACTTCCAGTTAA	1036
Db	2261	TTGCAAATAGGCATTTAAAATGTGAATTTGGAATCAGATGTCTCCATTACTTCCAGTTAA	2320
Qy	1037	AGTGGCATCATAGGTGTTTCCTAAGTTTTAAGTCTTGGATAAAAACTCCACCAGTGTCTA	1096
Db	2321	AGTGGCATCATAGGTGTTTCCTAAGTTTTAAGTCTTGGATAAAAACTCCACCAGTGTCTA	2380
Qy	1097	CCATCTCCACCATGAAGTCTGTTAAGGAAGCTTCATTTTTGTATATTCCCGCTCTTTTCT	1156
Db	2381	CCATCTCCACCATGAAGTCTGTTAAGGAAGCTTCATTTTTGTATATTCCCGCTCTTTTCT	2440
Qy	1157	CTTCATTTCCCTGTCTTCTGCATAATCATGCCTTCTTGCTAAGTAATTCAAGCATAAGAT	1216
Db	2441	CTTCATTTCCCTGTCTTCTGCATAATCATGCCTTCTTGCTAAGTAATTCAAGCATAAGAT	2500
Qy	1217	CTTGGAATAATAAAATCACAATCTTAGGAGAAAGAATAAAATTTGTTATTTTCCAGTCTC	1276
Db	2501	CTTGGAATAATAAAATCACAATCTTAGGAGAAAGAATAAAATTTGTTATTTTCCAGTCTC	2560
Qy	1277	TTGGCCATGATGATATCTTATGATTAAAAACAAATTAAATTTTAAAACACCTGAAGATAT	1336
Db	2561	TTGGCCATGATGATATCTTATGATTAAAAACAAATTAAATTTTAAAACACCTGAAGATAA	2620
Qy	1337	ATTAGAAGAAATTTGTGCACCCTCCACAAAACATACAAAGTTTAAAAGTTTGGATCTTTTT	1396
Db	2621	ATTAGAAGAAATTTGTGCACCCTCCACAAAACATACAAAGTTTAAAAGTTTGGATCTTTTT	2680
Qy	1397	CTCAGCAGGTATCAGTTGTAAATAATGAATTAGGGGCCAAAATGCAAAACGAAAAATGAA	1456
Db	2681	CTCAGCAGGTATCAGTTGTAAATAATGAATTAGGGGCCAAAATGCAAAACGAAAAATGAA	2740

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Qy	1457	GCAGCTACATGTAGTTAGTAATTTCTAGTTTGAAGTGAATTGAATATTGTGGCTTCATA	1516
Db	2741	GCAGCTACATGTAGTTAGTAATTTCTAGTTTGAAGTGAATTGAATATTGTGGCTTCATA	2800
Qy	1517	TGTATTATTTTATATTGTACTTTTTTCATTATTGATGGTTTGGACTTTAATAAGAGAAAT	1576
Db	2801	TGTATTATTTTATATTGTACTTTTTTCATTATTGATGGTTTGGACTTTAATAAGAGAAAT	2860
Qy	1577	TCCATAGTTTTTAATATCCCAGAAGTGAGACAATTTGAACAGTGTATTCTAGAAAACAAT	1636
Db	2861	TCCATAGTTTTTAATATCCCAGAAGTGAGACAATTTGAACAGTGTATTCTAGAAAACAAT	2920
Qy	1637	ACACTAACTGAACAGAAGTGAATGCTTATATATATTATGATAGCCTTAAACCTTTTTCCCT	1696
Db	2921	ACACTAACTGAACAGAAGTGAATGCTTATATATATTATGATAGCCTTAAACCTTTTTCCCT	2980
Qy	1697	CTAATGCCTTAACTGTCAAATAATTATAACCTTTTAAAGCATAGGACTATAGTCAGCATG	1756
Db	2981	CTAATGCCTTAACTGTCAAATAATTATAACCTTTTAAAGCATAGGACTATAGTCAGCATG	3040
Qy	1757	CTAGACTGAGAGGTAAACACTGATGCAATTAGAACAGGTACTGATGCTGTCAGTGTTTAA	1816
Db	3041	CTAGACTGAGAGGTAAACACTGATGCAATTAGAACAGGTACTGATGCTGTCAGTGTTTAA	3100
Qy	1817	CACTATGTTTAGCTGTGTTTATGCTATAAAAGTGCAATATTAGACACTAGCTAGTACTGC	1876
Db	3101	CACTATGTTTAGCTGTGTTTATGCTATAAAAGTGCAATATTAGACACTAGCTAGTACTGC	3160
Qy	1877	TGCCTCATGTAAC TCAAAGAAAACAGGATTTTCATTAAGTGCATTGAATGTGGCTATTTTC	1936
Db	3161	TGCCTCATGTAAC TCAAAGAAAACAGGATTTTCATTAAGTGCATTGAATGTGGATATTTTC	3220
Qy	1937	TCTAAGTTACTCATATTGTCCTTTGCTTGAATGCAATGCCGTGCAGATTTATGTGGCTGC	1996
Db	3221	TCTAAGTTACTCATATTGTCCTTTGCTTGAATGCAATGCCGTGCAGATTTATGAGGCTGC	3280
Qy	1997	TATTTTTATTTTCTGTGCATTACTTTAACACCTTAAAGGGAGAAGCAAACATTTCTTCT	2056
Db	3281	TATTTTTATTTTCTGTGCATTACTTTAACACCTTAAAGGGAGAAGCAAACATTTCTTCT	3340
Qy	2057	TCAGCTGACTGGCAATGGCCCTTTAACTGCAATAGGAAGAAAAAAAAAAGGTTTGTGTG	2116
Db	3341	TCAGCTGACTGGCAATGGCCCTTTAACTGCAATAGGAAGAAAAAAAAAAGGTTTGTGTG	3400
Qy	2117	AAAATTGGTGATAACTGGCACTTAAGATCGAAAAGAAATTTCTGTATACTTGATGCCTTA	2176
Db	3401	AAAATTGGTGATAACTGGCACTTAAGATCGAAAAGAAATTTCTGTATACTTGATGCCTTA	3460
Qy	2177	AGATGCCCAAAGCTGCCCAAAGCTCTGAAAGACTTTAAGATAGGCAGTAATGCTTACTAC	2236
Db	3461	AGATGCCCAAAGCTGCCCAAAGCTCTGAAAGACTTTAAGATAGGCAGTAATGCTTACTAC	3520
Qy	2237	AATACTACTGAGTTTTTGTAGAGTTAACATTTGATAATAAAACTTGCCTGTTTAATCTCA	2296
Db	3521	AATACTACTGAGTTTTTGTAGAGTTAACATTTGATAATAAAACTTGCCTGTTTAATCTCA	3580
Qy	2297	A 2297	
Db	3581	A 3581	

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or (d) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a) or (b).

With regard to claim 2, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is a cDNA (Abstract, where 20P2H8 comprises an approximately 3600 bp cDNA sequence which corresponds to SEQ ID NO:1).

With regard to claim 3, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is genomic DNA (p. 20, where the sequences include genomic DNA; and 22-23, where the process of isolating a genomic sequence from which the 20P2H8 sequence is expressed is taught).

With regard to claim 4, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is an RNA (p. 20, where the sequences include antisense and RNA sequences).

With regard to claim 5, Afar teaches an embodiment of claim 1, wherein the nucleic acid molecule is a mammalian nucleic acid molecule (p. 18, where it is noted that the sequence provided in Figure 1 is a human sequence of 20P2H8).

With regard to claim 6, Afar teaches an embodiment of claim 5, wherein the nucleic acid molecule is a human nucleic acid molecule (p. 18, where it is noted that the sequence provided in Figure 1 is a human sequence of 20P2H8).

With regard to claim 8-9, Afar teaches a vector and host cell comprising the nucleic acid molecule of claim 1 (p. 23, where vectors and host cells which include 20P2H8 sequences are discussed).

With regard to claim 16, Afar teaches a kit for detecting a risk of cancer or presence of cancer in a patient, said kit comprising a means for determining the presence of:

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- (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 113;
- (b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 12;
- (c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b) (see alignment above, where 20P2H8, which corresponds to SEQ ID NO:10 of Afar shares 85.7% similarity with the full length of SEQ ID NO:12); or
- (d) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a) or (b); or
- (e) a polypeptide of claim 12.

Conclusion

No claims are allowed. All claims stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM